

§ 170.6

21 CFR Ch. I (4–1–08 Edition)

§ 170.6 Opinion letters on food additive status.

(a) Over the years the Food and Drug Administration has given informal written opinions to inquiries as to the safety of articles intended for use as components of, or in contact with, food. Prior to the enactment of the Food Additives Amendment of 1958 (Pub. L. 85-929; Sept. 6, 1958), these opinions were given pursuant to section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads in part: “A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health”.

(b) Since enactment of the Food Additives Amendment, the Food and Drug Administration has advised such inquirers that an article:

(1) Is a food additive within the meaning of section 201(s) of the act; or

(2) Is generally recognized as safe (GRAS); or

(3) Has prior sanction or approval under that amendment; or

(4) Is not a food additive under the conditions of intended use.

(c) In the interest of the public health, such articles which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1), or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.

(d) Because of the time span involved, copies of many of the letters in which the Food and Drug Administration has expressed an informal opinion concerning the status of such articles may no longer be in the file of the Food and Drug Administration. In the absence of information concerning the names and uses made of all the articles referred to in such letters, their safety of use cannot be reexamined. For this reason all food additive status opinions of the kind described in paragraph (c) of this section given by the Food and

Drug Administration are hereby revoked.

(e) The prior opinions of the kind described in paragraph (c) of this section will be replaced by qualified and current opinions if the recipient of each such letter forwards a copy of each to the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, along with a copy of his letter of inquiry, on or before July 23, 1970.

(f) This section does not apply to food additive status opinion letters pertaining to articles that were considered by the Food and Drug Administration to be food additives nor to articles included in regulations in parts 170 through 189 of this chapter if the articles are used in accordance with the requirements of such regulations.

[42 FR 14483, Mar. 15, 1977, as amended at 54 FR 24896, June 12, 1989]

§ 170.10 Food additives in standardized foods.

(a) The inclusion of food ingredients in parts 170 through 189 of this chapter does not imply that these ingredients may be used in standardized foods unless they are recognized as optional ingredients in applicable food standards. Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the Act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the Act requires that the Secretary publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation,